registration form and comprehensive planning tool are available on the ACO ADS Web site at *https://acoregister.rti.org.*

This session is open to the public. However, space is limited and participants are encouraged to register as soon as possible. Registration for this session will remain open until the date specified in the **DATES** section of this notice or the seating capacity has been reached.

Participants are responsible for their own travel, parking, meals, and overnight-stay expenses. More information about the venue and accommodations can be found at *https://aco-adsregister.rti.org.*

Subsequent ADSs will be offered in other locations in different regions around the country at later dates to be determined. Information for all future ADSs will be posted online at *https://acoregister.rti.org* as they become available.

Authority: Section 1115A of the Act.

Dated: May 16, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2011–12342 Filed 5–17–11; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Measurement Development: Quality of Caregiver-Child Interactions for Infants and Toddlers (Q–CCIIT).

OMB No.: New Collection.

Description: The Office of Planning, Research and Evaluation (OPRE), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is proposing to develop a new observation measure to assess the quality of child care settings, specifically the quality of caregiver-child interaction for infants and toddlers in nonparental care. The measure will be appropriate for use across child care settings, center-based and family child care settings as well as single- and mixed-age classrooms.

The two-year data collection activity will include two phases: (1) A pilot test and (2) a psychometric field test. We will request information about the child care setting, its classrooms and families for recruitment into the study. Information will be collected through observations, focus groups, and questionnaires.

In the pilot and field tests, the new Q–CCIIT observation measure will include observing a small group activity structured with a common task and asking follow-up observation questions. Caregivers observed will also complete a background questionnaire. Focus groups to obtain stakeholder input on caregiver-child interactions will be conducted separately with parents, caregivers, and training and technical assistance providers. Focus group participants will also complete a demographic questionnaire. Parents of children served by caregivers will complete a questionnaire on their child's competencies related to cognitive, language/communication, and social-emotional development. Parents will complete this questionnaire, which will also include family and child characteristics, once in the pilot test and twice in the field test, at the start of the field test and 6 months later to assess growth.

The purpose of this data collection is to support the 2007 reauthorization of the Head Start program (Pub. L. 110–134), which calls for periodic assessments of Head Start's quality and effectiveness.

Respondents: Child care setting representatives (directors or owners), caregivers (center-based and family child care settings), parents of children in those child care settings, and training and technical assistance providers.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hour per response	Estimated annual burden hours
1. Child care setting recruitment form	190	1	0.5	95
2. Q–CCIIT measure—small group activity and follow-up	290	1	0.25	73
3. Caregiver background questionnaire	520	1	0.25	130
4. Focus group interview guide	20	1	1.90	38
5. Parent focus group demographic questionnaire	10	1	0.10	1
6. Caregiver focus group demographic questionnaire	5	1	0.10	1
7. Training and technical assistance provider focus group demographic questionnaire	5	1	0.10	1
8. Parent-report child competence questionnaire	880	2	0.75	1,320

Estimated Total Annual Burden Hours: 1,659.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, *Attn:* OPRE Reports Clearance Officer. *E-mail address: OPREinfocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: May 11, 2011.

Steven Hanmer,

OPRE Reports, Clearance Officer.

[FR Doc. 2011–12150 Filed 5–18–11; 8:45 am]

BILLING CODE 4184–22–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0301]

Ultra High Throughput Sequencing for Clinical Diagnostic Applications—Approaches To Assess Analytical Validity; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

The Food and Drug Administration (FDA) is announcing the following public meeting entitled "Ultra High Throughput Sequencing for Clinical Diagnostic Applications—Approaches To Assess Analytical Validity." The purpose of the public meeting is to discuss challenges in assessing analytical performance for ultra high throughput genomic sequencing-based clinical applications.

Date and Time: The public meeting will be held on June 23, 2011, from 8 a.m. to 6 p.m.

Location: The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, rm. 1503 (the Great Room), Silver Spring, MD 20993–0002. For parking and security information, please visit the following Web site: *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm*. The public meeting will also be available to be viewed online via Web cast.

Contact Person: Zivana Tezak, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5668, Silver Spring, MD 20993–0002, 301–796–6206, e-mail: *zivana.tezak@fda.hhs.gov*.

Registration and Requests for Oral Presentations: If you wish to attend or view the Web cast of the public meeting, you must register online at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm* (select the appropriate meeting from the list).

Provide complete contact information for each attendee, including name, title, affiliation, e-mail, and telephone number. Registration requests should be received by June 9, 2011.

If you wish to make an oral presentation during the open comment session at the meeting, you must indicate this at the time of registration. FDA has included general discussion topics for comment in section III of this document, Topics for Input. You should also identify which discussion topic you wish to address in your presentation. FDA will do its best to accommodate requests to speak. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and to request time for a joint presentation. FDA will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin.

Registration is free and will be on a first-come, first-served basis. Early registration is recommended because seating is limited. FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the public meeting will be provided on a space-available basis beginning at 7 a.m. Non-U.S. citizens are subject to additional security screening, and they should register as soon as possible.

If you need special accommodations due to a disability, please contact Susan Monahan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4321, Silver Spring, MD 20993–0002, 301–796–5661, e-mail: *susan.monahan@fda.hhs.gov* at least 7 days in advance of the meeting.

Streaming Web Cast of the Public Meeting: There will be a registration process for the Web cast, and it will be on a first-come, first-served basis (*maximum capacity:* 900). If you have never attended a Connect Pro meeting before, test your connection at: *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit: *http://www.adobe.com/go/connectpro_overview.* (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

Comments: FDA is holding this public meeting to discuss a number of questions regarding appropriate approaches to assess analytical validity of ultra high throughput sequencing for clinical diagnostic applications. The deadline for submitting comments to be presented at this public meeting is June 9, 2011.

Regardless of attendance at the public meeting, interested persons may submit either electronic or written comments on any discussion topic(s) to the open docket. The deadline for submitting comments to the docket is July 23, 2011. Submit electronic comments to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. In addition, if responding to specific topics as outlined in section III of this document, please identify the topic you are addressing. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

SUPPLEMENTARY INFORMATION:

I. Background

Ultra high throughput genomic sequencing technologies are currently extensively used in research and are entering clinical diagnostic use; they are expected to bring transformative public health applications. In order to effectively utilize new sequencing technologies for clinical applications, appropriate evaluation tools (*e.g.,* standards, well established criteria) are needed to determine the accuracy of the results. Any regulatory strategy for clinical tests based on ultra high throughput genomic sequencing will benefit from novel and scientifically agreed-upon approaches to analytical validation. FDA is holding this public meeting to start discussion on approaches that can provide the most useful information in establishing safety and effectiveness of genomic sequencing technologies when used clinically.

This public meeting seeks input from academia, Government, industry, and other stakeholders on validation methodologies, materials, and bioinformatics approaches needed to address unique analytical validation requirements of ultra high throughput sequencing based molecular diagnostics and confirm the sequencing quality and the accuracy of the tests. The ultimate goal is to accelerate and support the introduction of safe and effective innovative diagnostics in public health applications.

II. Meeting Overview

The public meeting will consist of presentations providing background on